

Application No.: 10/602747  
Docket No.: CL1686USDIV

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**REMARKS**

Claims 1-4, 8, 9, and 14-16 are under consideration in this application  
Claims 1-4, 8, 9 and 14-16 are rejected under 35 USC § 112  
No new matter has been added.

***Claim Rejections – 35 USC § 112, first Paragraph***

Claims 10, 11, 15 and 16 are rejected under 35 USC § 112, 1<sup>st</sup> paragraph for failing to comply with the written description requirement.

Claims 10 and 11 have been canceled previously and therefore this rejection is moot with respect to those claims.

The examiner argues the claims lack a description of the *yvaW* promoter region in the specification and thus the chimeric gene recited in the claims fails the written description requirement. Applicants respectfully traverse.

By way of clarification, claims 15 and 16 are dependant upon claims 1 and 2, but do not independently recite a chimeric gene. Claims 1 and 2 are not a subject of the stated rejection. Applicants respond here on the assumption that the rejection is applicable to claims 1, 2 and those dependant thereon.

It is axiomatic that which is well known to the skilled person need not be disclosed in detail in order to meet the written description requirement. See for example MPEP 2163 IIA3(a) which states:

“What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384, 231 USPQ at 94. If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. See, e.g., *Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating “the description need not be *in ipsiis verbis* [i.e., “in the same words”] to be sufficient”).” MPEP 2163 IIA3(a)

The examiner states that neither the prior art nor the specification teach the structural requirements of the promoter region of *yvaWXY* (page 3 of the present action). In fact, the genome of *Bacillus subtilis* was made available in 1997 in Nature 390 (6657), 249-256 (1997) and as Genbank accession number Z99121 AL009126 (partially reproduced below)

LOCUS BSUB0018 194692 bp DNA linear BCT 18-APR-2005  
DEFINITION Bacillus subtilis complete genome (section 18 of 21): from 3414339  
to 3609030.  
ACCESSION Z99121 AL009126  
VERSION Z99121.2 GI:32468825

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## KEYWORDS

SOURCE *Bacillus subtilis* subsp. *subtilis* str. 168ORGANISM *Bacillus subtilis* subsp. *subtilis* str. 168Bacteria; Firmicutes; Bacillales; Bacillaceae; *Bacillus*.

REFERENCE 1 (bases 1 to 194692)

AUTHORS Kunst, F., Ogasawara, N., Moszer, I., Albertini, A.M., Alloni, G., Azevedo, V., Bertero, M.G., Bessières, P., Bolotin, A., Borchert, S., Borriss, R., Boursier, L., Brans, A., Brann, M., Brignell, S.C., Bron, S., Brouillet, S., Bruschi, C.V., Caldwell, B., Capuano, V., Carter, N.M., Choi, S.K., Codani, J.J., Connerton, I.F., Cummings, N.J., Daniel, R.A., Denizot, F., Devine, K.M., Dusterhoft, A., Ehrlich, S.D., Emmerson, P.T., Entian, K.D., Errington, J., Fabret, C., Ferrari, E., Foulger, D., Fritz, C., Fujita, M., Fujita, Y., Fuma, S., Galizzi, A., Galleron, N., Ghim, S.Y., Glaser, P., Goffeau, A., Golightly, E.J., Grandi, G., Giuseppe, G., Guy, B.J., Haga, K., Haiech, J., Harwood, C.R., Henaut, A., Hilbert, H., Holsappel, S., Hosono, S., Hulio, M.F., Itaya, M., Jones, L., Joris, B., Karamata, D., Kasahara, Y., Klaerr-Blanchard, M., Klein, C., Kobayashi, Y., Koetter, P., Koningsstein, G., Krogh, S., Kumano, M., Kurita, K., Lapidus, A., Lardinois, S., Lauber, J., Lazarevic, V., Lee, S.M., Levine, A., Liu, H., Masuda, S., Maucel, C., Medigue, C., Medina, N., Mellado, R.P., Mizuno, M., Moestl, D., Nakai, S., Noback, M., Noone, D., O'Reilly, M., Ogawa, K., Ogiwara, A., Oudega, B., Park, S.H., Parro, V., Pohl, T.M., Portetelle, D., Porwollik, S., Prescott, A.M., Presecan, E., Pujic, P., Purnelle, B., Rapoport, G., Rey, M., Reynolds, S., Rieger, M., Rivolta, C., Rocha, E., Roche, B., Rose, M., Sadaie, Y., Sato, T., Scanlan, E., Schleich, S., Schroeter, R., Scoffone, F., Sekiguchi, J., Sekowska, A., Serror, S.J., Serror, P., Shin, B.S., Soldo, B., Sorokin, A., Tacconi, E., Takagi, T., Takahashi, H., Takamaru, K., Takeuchi, M., Tamakoshi, A., Tanaka, T., Terpstra, P., Tognoni, A., Tosato, V., Uchiyama, S., Vandenbol, M., Vannier, F., Vassarotti, A., Viari, A., Wambutt, R., Wedler, E., Wedler, H., Weitzenegger, T., Winters, P., Wipat, A., Yamamoto, H., Yamane, K., Yasumoto, K., Yata, K., Yoshida, K., Yoshikawa, H.F., Zumstein, E., Yoshikawa, H. and Danchin, A.

TITLE The complete genome sequence of the gram-positive bacterium *Bacillus subtilis*

JOURNAL Nature 390 (6657), 249-256 (1997)

48218..48760

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/gene="yvaW"

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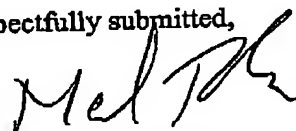
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The above excerpt from the Genbank record of the full genome of *Bacillus subtilis* indicates that the coding region of *yvaV* ends at base 48760 and the coding region of *yvaW* begins at base 48982. The skilled person will recognize that the promoter region will lie upstream of the *yvaW* coding region prior to the start of the *yvaV* coding region and would easily be able to discern the portion of the genome containing the promoter region in question.

Applicants submit that the discovery of the invention was the finding that the *yvaWXY* promoter was activated in the absence of oxygen, and the person of skill in the art, looking to the teaching of the prior art in view of the specification would reasonably conclude that the applicant was in possession of the invention at the time the application was filed.

In view of the foreign Applicants respectfully request reconsideration of the claims as amended and removal of all rejections.

Respectfully submitted,



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